

50. (New) A radiographic marker as defined in claim 46, wherein the partially radiopaque, partially radiolucent material includes metal and plastic having an overall thickness of about 0.040 inches.

51. (New) A radiographic marker as defined in claim 50, wherein the partially radiopaque, partially radiolucent material includes metal and plastic having an overall thickness of about 0.015 to about 0.040 inches.

52. (New) A radiographic marker as defined in claim 50, wherein the plastic is impregnated with the metal.

53. (New) A radiographic marker as defined in claim 52, wherein the plastic is impregnated with barium.

Remarks

Claims 1-19 have been canceled, new claims 20-53 have been added, and therefore claims 20-53 are pending in this application. No new matter has been added.

The undersigned thanks Examiner Church for courteously discussing this application by telephone interview, during which the claims were discussed with reference to the prior art references of record. For the reasons discussed during the interview and summarized below, it is respectfully submitted that the claims are allowable.

Claims 1, 2, 6 and 10-19 were rejected under 35 U.S.C. § 112, second paragraph. In view of the cancellation of these claims, and the introduction of the new claims above, it is respectfully submitted that this ground for rejection has been obviated.

Claims 1-19 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,469,847 to Zinreich et al., and in the alternative, were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,193,106 to DeSena. The Examiner's grounds for rejection are hereinafter traversed, and reconsideration is respectfully requested, particularly in view of the clarifying amendments made through introduction of the new independent claims.

First, new independent claim 20 is commensurate in scope to the claims allowed in parent application serial no. 08/934,121, now U.S. Patent No. 6,041,094, and therefore should be allowable for the same reasons that the independent claims were allowed in the parent application.

Second, neither Zinreich et al. nor DeSena teach or suggest providing a marker made of a partially radiopaque, partially radiolucent material, wherein the density and thickness of that material is selected to absorb from about 2% to about 75% of the radiation, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail of the tissue clearly visible through the radiographic shadow of the marker, as recited in independent claims 20, 36 and 46.

To the contrary, Zinreich et al. teach a multi-modality marker, i.e., one that can be used with multiple imaging methods, such as x-ray, CT, ultrasound, PET, MRI and others. (See col. 3, lines 5-11). For x-ray applications, Zinreich et al. specifically teach the use of radiopaque materials. More specifically, Zinreich et al. state that the gel 12 "is sufficiently *X-Ray-opaque* for adequate imaging on CT or X-Ray." (Col. 3, line 65 through col. 4, line 1; emphasis added). Zinreich et al. further teach that additional x-ray opaque materials may be used in addition to the radiopaque gel 12: "an *X-Ray-opaque* metal, metallic powder or particles, or metallic salt (e.g.,

barium sulfate) may be laid into the outer casing 20 in addition to the gel 12.” (Col., 6, lines 9-15; emphasis added).

Thus, Zinreich et al. in no way teach or suggest employing a partially radiopaque, partially radiolucent material in order to generate a radiographic image of the tissue with the shadow of the marker superimposed thereon, and the anatomical detail present in the tissue clearly visible through the radiographic shadow of the marker, as recited in independent claims 1, 36 and 46. Rather, Zinreich et al. teach placing the marker to the side of the tissue to be viewed, and generating either a “heavy, bright” or “heavy, dark” image of the radiopaque marker. Zinreich et al. state: “In images created from either MRI or X-Ray modalities (including CT) a marker 10 appears in side view as a *heavy, bright line* on a negative image or a *heavy, dark line* on a positive image. If the image is taken perpendicular to a top surface 11 of the marker 10, the marker 10 appears as a *bright disk shape* on negative images or as a *dark disk shape* on positive images.” (Col. 5, lines 4-9; emphasis added).

The passages in Zinreich et al. cited by the Examiner do not change this clear teaching away from the present invention. The passage at column 3, lines 2-5 of Zinreich et al. stating that the multi-modality surface markers “do not produce undesirable images which obscure portions of desirable images”, is merely referring to the production of “streak artifacts” that occur when CT imaging with some prior art markers. This problem is also described, for example, in the “background” portion of the present application at page 2, lines 6-13. Moreover, the fact that Zinreich et al.’s markers may not produce streak artifacts (i.e., undesirable images that can obscure portions of other desirable images) in no way teaches or suggests the provision of partially radiopaque, partially radiolucent markers that allow anatomical detail falling within

the marker's shadow to be clearly visible on the image, as recited in independent claims 20, 36 and 46.

Like Zinreich et al., DeSena also is directed specifically to radiopaque markers. In each instance, DeSena's markers are described as "radiopaque". DeSena states: "Said marker devices 3 comprise a pressure sensitive adhesive medical tape 1 onto which a flexible *radiopaque* material is affixed." (Col. 4, lines 31-34; emphasis added). Similarly, DeSena describes the markers as "radiopaque" at col. 4, lines 52-54 ("the radiopaque material"), and column 5, lines 7-10 ("said radiopaque material"). Because DeSena's markers are radiopaque they would obscure radiographic detail if placed directly over the area of interest. Accordingly, DeSena further teaches forming the markers in perimeter shapes that "are large enough to *encompass* the region of interest". (Col. 3, lines 65-66; emphasis in original). Clearly, DeSena teaches avoiding the danger of obscuring radiographic detail not by making the marker partially radiolucent, as recited in the present claims, but by placing the radiopaque marker around and outside of the area of interest. (See also col. 5, lines 7-11 and limitation "b" of claim 1 of DeSena). Thus, to modify the markers disclosed by DeSena in the manner suggested by the Examiner would be contrary to the express teachings of DeSena.

A significant advantage of the present invention is that the image of the partially radiopaque, partially radiolucent marker is superimposed over the image of the tissue with the anatomical detail present in the tissue clearly visible through the radiographic shadow of the marker, as recited in independent claims 20, 36 and 46. As a result, the marker cannot block the image of any underlying anatomical detail, nor can the image of the marker itself be mistaken for anatomical detail. Zinreich et al. and DeSena show no recognition of these problems, much less teach a solution to these problems as recited in independent claims 20, 36 and 46. Although the

Examiner asserts that it would have been obvious to adjust the thickness or percentage of attenuation of the markers shown in either Zinreich et al. or DeSena, the Office Action fails to point to any specific teaching in the prior art references of record suggesting modification of these prior art markers to be partially radiopaque and partially radiolucent, much less any teaching to generate radiographic images of the markers with anatomical detail of the tissue clearly visible through the shadow of the marker, as recited in the independent claims.

Accordingly, it is respectfully submitted that independent claims 20, 36 and 46 are unobvious in view of Zinreich et al. and DeSena for at least these reasons. Because claims 21-35, 37-45, and 47-53 each depend from, and therefore include all of the limitations of one of these independent claims, it is respectfully submitted that these dependent claims likewise are unobvious over the prior art references of record for the same reasons as the independent claims, and for reciting additional patentable subject matter.

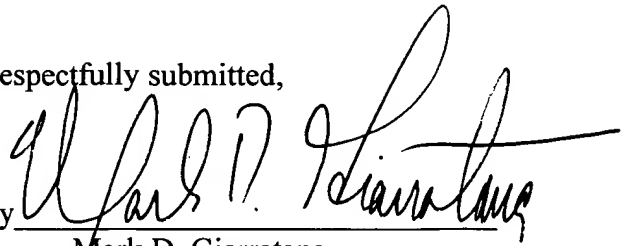
Authorization is hereby given to charge our Deposit Account No. 11-0231 in the amount of \$117.00 to cover the fee for the extra claims over 20 (13 claims x \$9.00 per claim). No fee in addition to those submitted herewith is believed to be required; however, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our deposit account no. 11-0231.

If the Examiner wishes to further discuss any of the issues herein, or otherwise if it would

facilitate the examination of this application, please call the undersigned at the telephone number below.

Respectfully submitted,

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